K090199

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Wuxi Jiajian Medical Instrument Co., Ltd
Qinghong Rd., Ehu Town, Xishan District, Wuxi, China
Phone: 0510-88745788 Fax: 0510-88746629 URL: www.jiajian-healthcare.com

JIAJIAN 佳健医疗

Section 4
Premarket Notification [510(k)] Summary
[As required by CFR 21 807.92(c)]

AUG 1 1 2009

Date: July 10t^{h}, 2009

Submitter: Wuxi Jiajian Medical Instrument Co., Ltd
Qinghong Rd., Ehu Town, Xishan District, Wuxi, China 214116

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US Agent: Mark Thomas
E-mail: thomas_fda@yahoo.com
Tel: 510-6522489
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Device Summary:

Trade Name:	Jiajian Acupuncture Needle
Common or Usual Name:	Acupuncture needle
Classification Name:	needle, acupuncture, single use
Product Code:	MQX
Regulation Number:	880.5580
Medical Specialty:	General Hospital
Device Class:	II
Device Description:	Jiajian brand Acupuncture Needle consists of a stainless steel wire (ASTM 304) as the needle body, with a stainless steel wire handle, a copper wire handle or polystyrol handle. The handles make the needles easier to manipulate and place. The acupuncture needle is sterilized and disposable. The diameter of the needle is 0.14~0.80mm; the length of the needle is 7~100mm; the invasive length is 2~47mm.
Indications for use:	Jiajian Acupuncture Needle is intended to piece the skin in the practice of acupuncture therapy by qualified practitioners or acupuncture doctors as determined by the states.
Sterilization:	Jiajian Acupuncture Needles are sterilized and manufactured in a clean room meeting Standard ISO 14644-2. The devices are supplied sterile and are single use only. Do not attempt to resterilized product once the package has been opened. Sterilization method: The needles are sterilized by Co-60 irradiation at a validated dose level of 25kGy. The sterilization process is applied on finished devices following final packaging. The sterilization process is applied in accordance with Standards ISO 11137-1 by a qualified sterilizers from Accredited Sterilization Institue. Validation method used to validate sterilization cycle: The radiation dose level has been validated to get the sterility assurance level of 10^{-6} in

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accordance with Standard ISO 11737-1.

Substantial Equivalence Infomration:

1) Predicate Device:

510(k) Number:	K983800
Marketing clearance date:	August 27th, 1999
Product name:	DN Acupuncture Needles
Manufacturer:	Buckman Company, Inc.
510(k) Number:	K974616
Marketing clearance date:	February 5th, 1998
Product name:	Singer Acupuncture Needles
Manufactuer:	Lorac, Inc.

2) Comparison with predicate device

Similarities:	1) Similar materials composition and structure;
	2) Same intended use;
	3) All are sterile;
	4) All are used as prescription
Differences:	1) Different sizes scale

3) Conclusion: Jiajian Acupuncture Needle is substantially equivalent to acupuncture needles sold in the US market. It is SE to the following brand of acupuncture needles available in the US market:
DN Acupuncture Needles (K983800)
Singer Acupuncture Needles (K974616)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Doris Dong
Manager
Wuxi Jiajian Medical Instrument Company, Limited
Qinghong Rouad, Ehu Town, Xishan District
Wuxi, Jiangsu 214116
CHINA

AUG 11 2009

Re: K090199
Trade/Device Name: Jiajian Acupuncture Needle
Regulation Number: 21 CFR 880.5580
Regulation Name: Acupuncture Needle
Regulatory Class: II
Product Code: MQX
Dated: July 10, 2009
Received: July 28, 2009

Dear Ms. Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony O. Watson for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090199

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Section 3
Statement of Indications for Use

510(k) Number (if known): K090199

Device Name: Jiajian Acupuncture Needle

Indications for Use:

Jiajian Acupuncture Needle is intended to piece the skin in the practice of acupuncture therapy by qualified practitioners or acupuncture doctors as determined by the states.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K090199